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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 09/742,993 | 12/20/2000 | Mark Pines | C07/8 8795 | |
| 7590 02/09/2005 | | | EXAMINER | |
| Jane T. Gunnison | | | COOK, REBECCA | |
| Fish & Neave | | | | |
| 1251 Avenue of the Americas | | | ART UNIT | PAPER NUMBER |
| New York, NY 10020-1105 | | | 1614 | |
| | | | | |

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Ar | oplication No. | Applicant(s) | | | |
|--|--|---|---|--|--|--|--|
| | | 09 | 9/742,993 | PINES ET AL. | | | |
| | Office Action Summary | Ex | aminer | Art Unit | | | |
| | | | ebecca Cook | 1614 | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SH THE - Exte after - If the - If NO - Failu Any | ORTENED STATUTORY PERIOD F MAILING DATE OF THIS COMMUN nsions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this common the proof of t | ICATION. of 37 CFR 1.136(a). nunication. 0) days, a reply with atutory period will ap will, by statute, caus | In no event, however, may a reply be timing the statutory minimum of thirty (30) days oply and will expire SIX (6) MONTHS from the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) file | ed on <u>20 Decer</u> | mber 2000. | | | | |
| 2a)□ | | | ion is non-final. | | | | |
| 3)□ | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposit | ion of Claims | | | | | | |
| 5)□ 6)⊠ 7)□ | 4) Claim(s) 1-3 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-3 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicat | ion Papers | | | | | | |
| 10)⊠ | The specification is objected to by the The drawing(s) filed on 20 December Applicant may not request that any object Replacement drawing sheet(s) including The oath or declaration is objected to | <u>r 2000</u> is/are: ction to the draw the correction i | ving(s) be held in abeyance. See is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| Attachmen | ıt(s) | | | | | | |
| _ | ce of References Cited (PTO-892) | | 4) Interview Summary | (PTO-413) | | | |
| 2) Notice 3) Infor | ce of Draftsperson's Patent Drawing Review (F mation Disclosure Statement(s) (PTO-1449 or er No(s)/Mail Date | | Paper No(s)/Mail Da | | | | |

DETAILED ACTION

Reissue Application Declaration Defective

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414. The error in the formula is not described in sufficient detail as to how the structure is erroneous/incomplete.

Abstract Objected To

The abstract of the disclosure is objected to because it does not disclose the correct formula of the compound now claimed. Correction is required. See MPEP § 608.01(b).

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the word "compounds" is confusing, since only one compound is disclosed. It is not clear to whom the compound is administered. It is not clear that the subject is in need of treatment. Amending the claim to recite "[A] method for the treatment of a tumor sensitive to the compound below in a subject in need of said treatment comprising...." will overcome this rejection.

It is not clear that claim 2 is a dependent claim. Dependent claims should begin with the word "[T]he" to make their dependent status clear. Furthermore, it is not clear why halofuginone begins with a capital "h."

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There is no antecedent basis in claim 3 for the word "cancer." Amending the claim to recite "...wherein the tumor is a tumor in ..." will overcome this claim. Support for this recitation is inherent in the disclosure in column 17. The word "cervix" is misspelled.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,420,371. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one of ordinary skill in the art that the method of '371, which uses the instant compound for the inhibition of angiogenesis, would also be useful to treat a tumor. That is because angiogenesis is known to promote the growth of tumors and by inhibiting angiogenesis the growth of tumors would also be inhibited.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

Lucalook

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Primary Examiner

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February 7, 2005